

## **REMARKS**

### ***Summary of Changes Made***

The Application was filed with 27 claims. The 27 original claims were canceled and new claims 28 - 52 were added. Claims 42 and 46-52 were previously canceled, and claims 28 and 43 were previously amended. Presently, claim 41 is canceled, and claims 28, 30, and 40 are amended. Accordingly, claims 28-40 and 43-45 (16 claims) remain pending in the application. No new matter is added herewith.

### ***Claim Rejections – 35 U.S.C. § 112, second paragraph***

Claims 28-41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner contends that claims 28, 30, and 40 each recite both a broad range or limitation (arthropods as the broad limitation, and ticks/mites as the narrow limitation).

Claim 41 allegedly suffers a similar condition in further limiting “arthropods” to “lymph- or bloodsucking insects and/or skin penetrating arthropods,” all while depending from claim 28, which recites ticks and mites.

The Examiner will note that claim 41 has been canceled thus rendering the rejection thereof moot. Also, claims 28 and 30 have been amended to recite only that ticks and mites are the target of action of the method of repelling. Said amendments render all affected claims clear, precise, and definite. Applicants respectfully request withdrawal of the rejection.

### ***Claim Rejections – 35 U.S.C. § 103(a) (Uick/ Abivardi/ Beldock)***

Next, claims 28, 29, 31-33, 36-41, and 43-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Uick, U.S. Pat. No. 5,716,602, (“Uick”) in view of Abivardi, Iranian Entomology an Introduction - Applied Entomology Vol. 2, (“Abivardi”), as evidenced by Beldock et al., U.S. Pat. No. 5,648,398, (“Beldock”).

The Examiner contends that Uick discloses an insect repellent sunscreen comprising DEET, octyl methoxycinnamate, fragrance, emulsifiers, and water which can be applied onto human skin for protection outdoors against annoyance by pests and the harmful effects of UV rays. The Examiner admits that Uick fails to teach that the repellent composition comprises a

portion or extract of the plant *Vitex agnus castus*.

Accordingly, the Examiner cites Abivardi for an alleged teaching of a composition of pine seed with leaves of *Vitex agnus castus* that can be cooked in olive oil and rubbed onto the entire body as a repellent against insects. Furthermore, Abivardi teaches that the leaves of *Vitex agnus castus* can be scattered in the house including on the floors in order to repel insects or vermin by their odor.

The Examiner cites Beldock as evidence that DEET is effective against Lyme disease ticks, and concludes that it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to add the leaves of *Vitex agnus-castus* as an insect repellent to the composition of Uiek, as suggested by Abivardi and produce the instant invention. The Examiner believes that the skilled artisan would have been motivated to do this because Abivardi teaches that the leaves of *Vitex agnus castus* act as an insect repellent.

Based on Beldock, the Examiner takes the position that a composition comprising DEET would necessarily act as a tick repellent. The Examiner concludes that it would have been obvious to use the leaves of *Vitex agnus-castus* as an insect repellent to be added to the composition taught by Uiek in order to enhance the insect repellency activity of the composition.

To properly determine a *prima facie* case of obviousness, the Examiner "must step backward in time and into the shoes worn by the hypothetical 'person of ordinary skill in the art' when the invention was unknown and just before it was made," M.P.E.P. 2142. Three criteria may be helpful in determining whether claimed subject matter is obvious under section 103(a): first, if there is some suggestion or motivation to modify or combine the cited references; second, if there is a reasonable expectation of success; and third, if the prior art references teach or suggest all the claim limitations, *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 127 S.Ct. 1727 (2007). With regard to the first criterion, the mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. In *re Mills*, 916 F.3d 690 (Fed. Cir. 1990). "Knowledge in the prior art of every element of a patent claim ... is not of itself sufficient to render the claim obvious," *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966); *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1333-34 (Fed. Cir. 2002). The issue is whether there is an apparent reason to combine the known elements in the fashion claimed by the patent at issue. *KSR Int'l Co. v. Teleflex, Inc.*

The Examiner has cited three references, which, when taken together, appear to dislose all limitations of the rejected claims. However, the Examiner, in merely pointing out the existence of all limitations of a claim in a collection of prior art references does not establish the unpatentability of such claim. Indeed, neither the prior art nor the knowledge of the skilled artisan suggests the desirability of the combination of Uick, Abivardi and Beldock. Uick is cited only for a disclosure of DEET, a purely chemical insect repellent. It has no relation to the instantly disclosed composition as no DEET is present therein. Further, Uick fails to disclose or suggest any plant extract whatsoever, and in particular, fails to disclose *Vitex agnus castus*.

The key to the instant rejection appears to be Abivardi's teaching that leaves of *Vitex agnus-castus* can be cooked with olive oil and pine seed to repel insects. However, insects are not arachnids. Indeed, ticks and mites are completely different from mosquitoes. Ticks and mites are arachnids (arachnida), whereas mosquitoes are insects (insecta). In particular, arachnids have 8 legs, an undivided body and no wings. Arachnids bite and draw blood for a period of up to 12 days continuously, and when they do, they bite and draw blood from the upper layers of the skin. Arachnids draw blood in all development stages: larva, nymph and adult. They develop in a dry environment and have a lifetime of 3-10 years.

On the other hand, mosquitoes have 6 legs and a body which is divided into three parts with wings. They bite and draw blood for a period of only several seconds, bite directly into blood vessels and only female adults bite and draw blood. Mosquitoes are born in and develop in the water, and their lifetime is only 1 to 2 months.

Namely, insects recognize their host, e.g. humans, from a distance, up to 100 meters. Consequently, insect repellents are volatile substances, in particular essential oils, which remain on the skin only for a short period. Cigarette smoke acts in a similar way to repel insects.

On the other hand, ticks do not recognize their host from a distance, but get onto a host when it comes in contact with the grass or plants on which they are sitting. Only elose proximity of the host attraets a tick. Repellents against ticks, therefore, must remain on the skin for a long time. Ticks are not repelled by cigarette smoke.

Known insect repellents, such as lemongrass oil, lemon oil, clove oil or many other etheric (i.e., essential) oils, have no repelling effect on ticks and mites. Chemical insect repellents, in particular the well known DEET, as well as Icaridine, have a very weak effect on ticks. Thus, in commercial repellents against ticks, the active ingredients have to be used in a

very high concentration compared to repellents against mosquitoes. In the context of these facts, the prior art has to be evaluated as follows.

Based on the stark differences between arachnids and mosquitoes (insects), it cannot be expected that a repellent which is appropriate for repelling insects such as mosquitoes is also effective as a repellent against arachnids such as ticks and mites.

Further, the Examiner appears to proceed from an assumption that plant extracts have generalizable activities and effects, i.e., that when the activity of one plant extract is known, such knowledge will arguably foretell the activity of another plant extract. This is incorrect. Constituents of plant extracts vary widely, even among species within the same family or genus. It cannot be presumed that if a first plant extract has a repellent activity against certain *insects*, than an extract from a completely different plant would necessarily have a repellent effect against ticks and mites, i.e., *arachnids*.

The present invention involves only extracts from *Vitex agnus castus*, not extracts from the broader genus *Vitex* in general, since even between different species of the same genus, there are significant differences in the components of such extracts. For example, even the plant *Vitex agnus castus* as presently claimed has different components than *Vitex rotundifolia*. That means, even within one genus there are significant differences in the components of the various species.

It is well known that certain plant extracts such as citrus oil can act as a repellent against insects, in particular mosquitoes. However, from this repellent property against insects, it cannot be concluded that there is also an activity against ticks and mites, which are completely different animals (arachnids). In the same way, from an insect repellent activity of one plant extract, it cannot be concluded that any other plant extract would also show an insect repellent activity, that alone a repellent activity against ticks and mites.

Mosquito repellence activity (i.e., insect repellence), as evaluated against *Aedes aegypti* was mainly confined to the most polar fractions of a plant extract, (Hebbalkar, et al., 1992; Mosquito repellent activity of oils from *Vitex negundo* leaves). In contrast, the repellent constituents of *Vitex agnus-castus* seeds are extractable only with *non-polar* solvents.

Based on the foregoing, it is unforeseeable that extracts of *Vitex agnus-castus* would have a repellent effect against arachnids, and therefore the Examiner's *prima facie* case of obviousness fails. Applicants believe the non-obviousness of the presently claimed invention has been established, and withdrawal of the rejection is respectfully requested.

***Claim Rejections – 35 U.S.C. § 103(a) (Uick/ Abivardi/ Beldock)***

Claims 30, 34 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Uick, in view of Abivardi, and further in view of Blum et al., U.S. Pat. No. 5,885,600, previously cited, (“Blum”), as evidenced by Beldock. The Examiner admits that Uick and Abivardi fail to teach a repellent composition comprising antioxidant. The Examiner believes that this deficiency is cured by the teachings of Blum, with its alleged teachings that insect repellents are used to prevent insects from annoying humans and animals, as well as repellents in general, which have been used to prevent insect harm to such items as food, clothing, and furniture.

Initially, Applicants note that the patentability of claim 28 has been established amply hereinabove. Each of claims 30, 34, and 35 ultimately depends from claim 28. The additional citation of Blum does not disturb the patentability of claim 28, and hence claims 30, 34, and 35 are patentable over the cited prior art combination.

Applicants further note that Blum discloses a variety of oils and extracts wholly unrelated to the instantly claimed compositions, in particular, neem, citronella and cedar oil. Applicants note that *Vitex agnus castus* is from the family Verbenaceae, while Cedar oil is derived from cedar wood (family Pinaceae), citronella is an extract of citrus fruit (family Rutaceae) and Neem is derived from the Neem tree, (*Azadirachta indica*, of the family Mellaceae). There is no relationship among the extracts of Blum and those instantly claimed.

Blum discloses insect repellents from cold processed extracted oils and an antioxidant, in particular oils from Neem, Citronella, and Cedarwoods. The focus is on insects (Abstract), although in col. 6, line 20 ticks and mites are mentioned. Applicants note that, by cold-pressing and addition of antioxidants, the effectiveness of the repellent can be maintained for a long time. As does the instant specification, Blum discloses that essential oils from plants have long been known as insect repellents. The document is completely silent about *Vitex agnus castus* or any species of *Vitex*. The disclosure of Blum is not enabling for a repellent against ticks, as there is no example showing any effect against them. It appears that the citation of Blum stands for the Examiner’s apparent belief that any plant extract or essential oil can be used to repel insects.

Based on the foregoing, Applicants assert the patentability of claims 30, 34, and 35, and respectfully request withdrawal of the rejection.

## **CONCLUSION**

Based on the foregoing, the Applicants respectfully request entry of the instant amendment and a Notice of Allowability for claims 28-40 and 43-45. If it is determined that the application is not in a condition for allowance, the Examiner is invited to initiate a telephone interview with the undersigned attorney to expedite prosecution of the present application. If there are any additional fees resulting from this communication, please charge the same to our Deposit Account No. 18-0160, our Order No. GIL-16108.

Respectfully submitted,

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